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(54) **METHODS AND APPARATUS FOR HEMOSTASIS FOLLOWING ARTERIAL CATHETERIZATION**

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See application file for complete search history.

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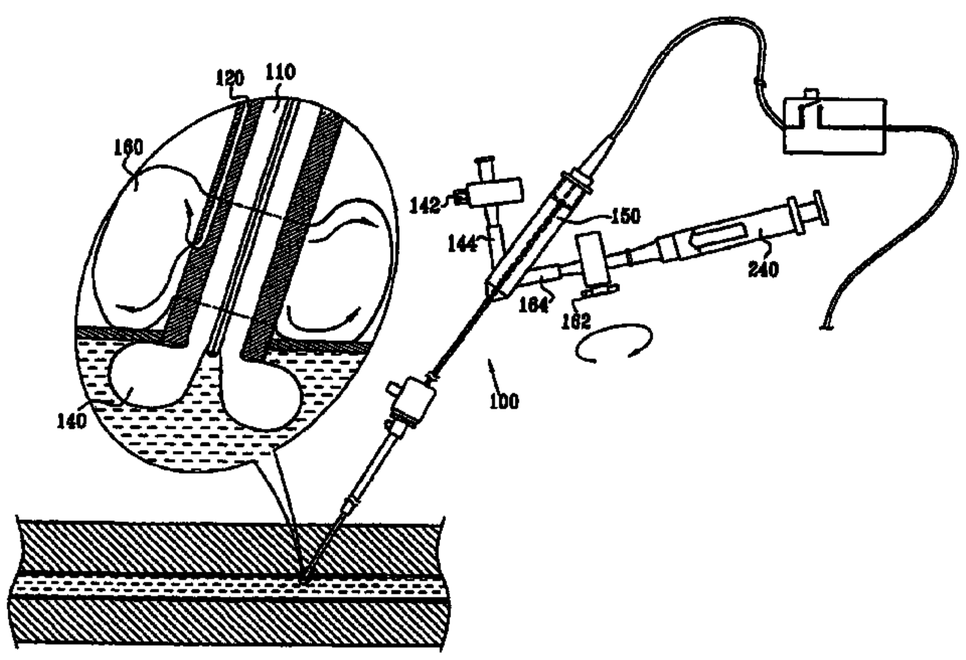
(57) **ABSTRACT**

A method for producing hemostasis of an artery of a patient having a puncture following arterial catheterization including introducing a hemostasis device including at least one electrode into the vicinity of the puncture, supplying an electric current to the at least one electrode, thereby heating blood in the vicinity of the puncture and causing coagulation of the blood and subsequently removing the hemostasis device from the patient.

16 Claims, 11 Drawing Sheets



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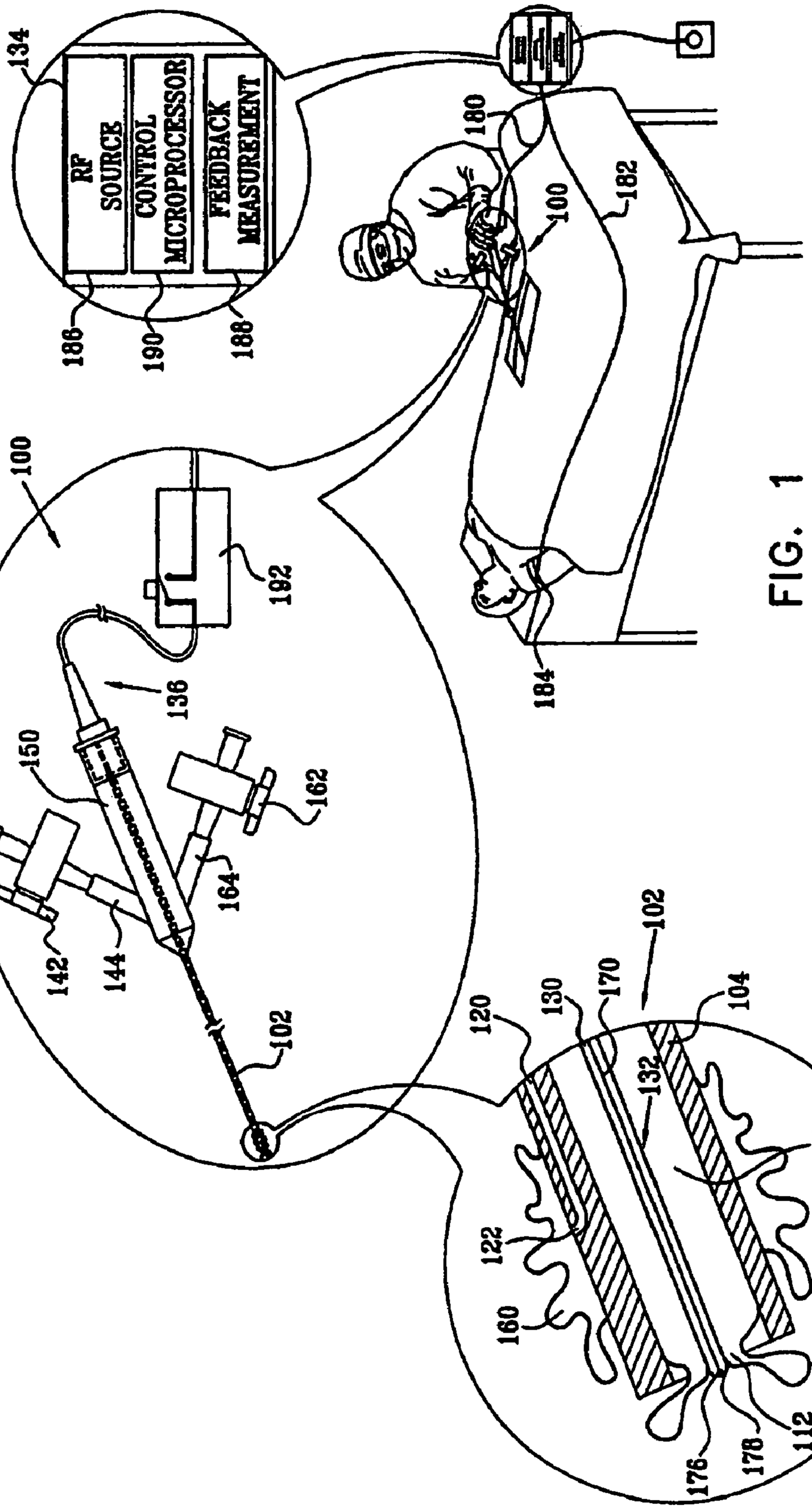
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FIG. 1

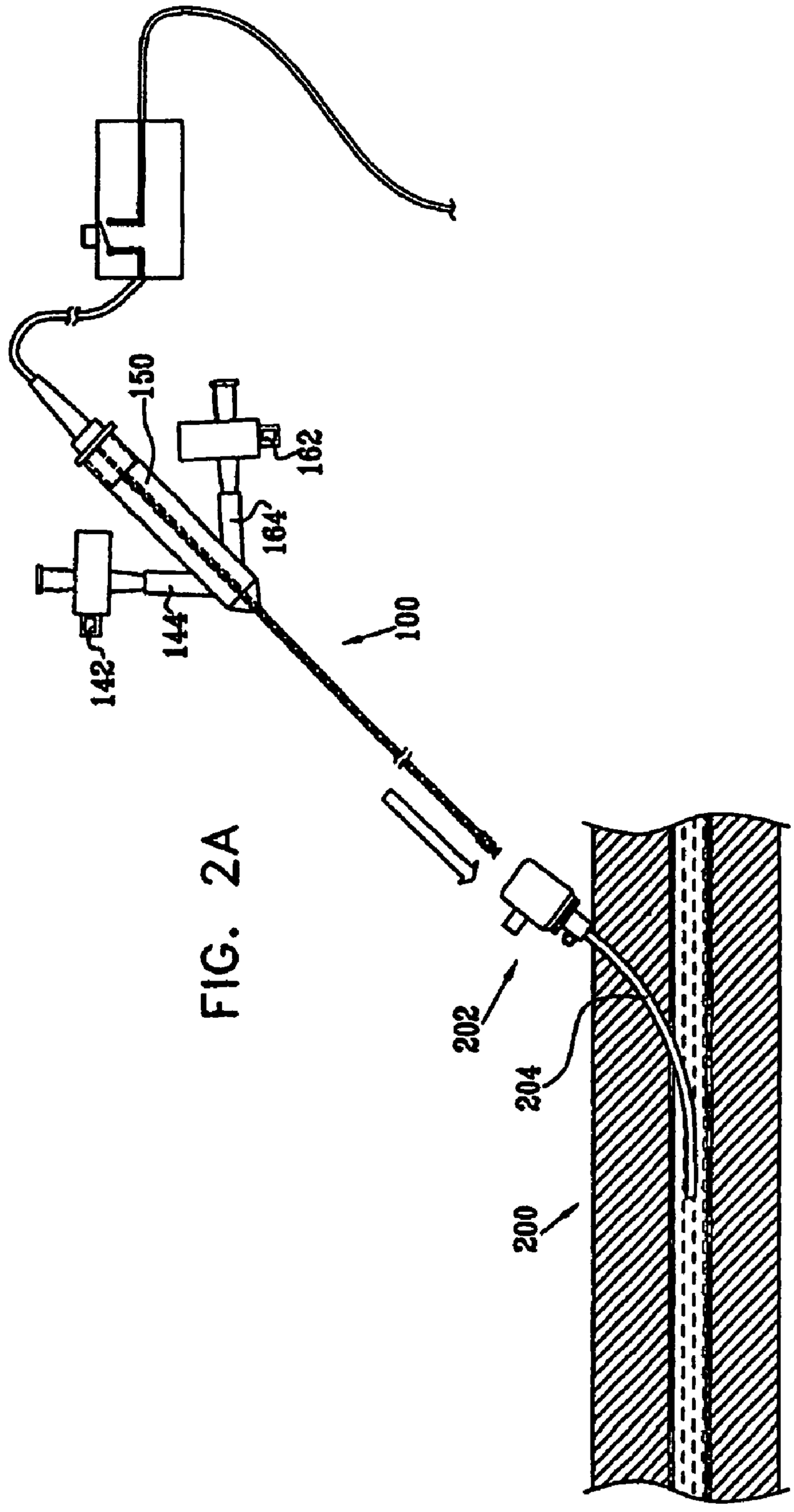
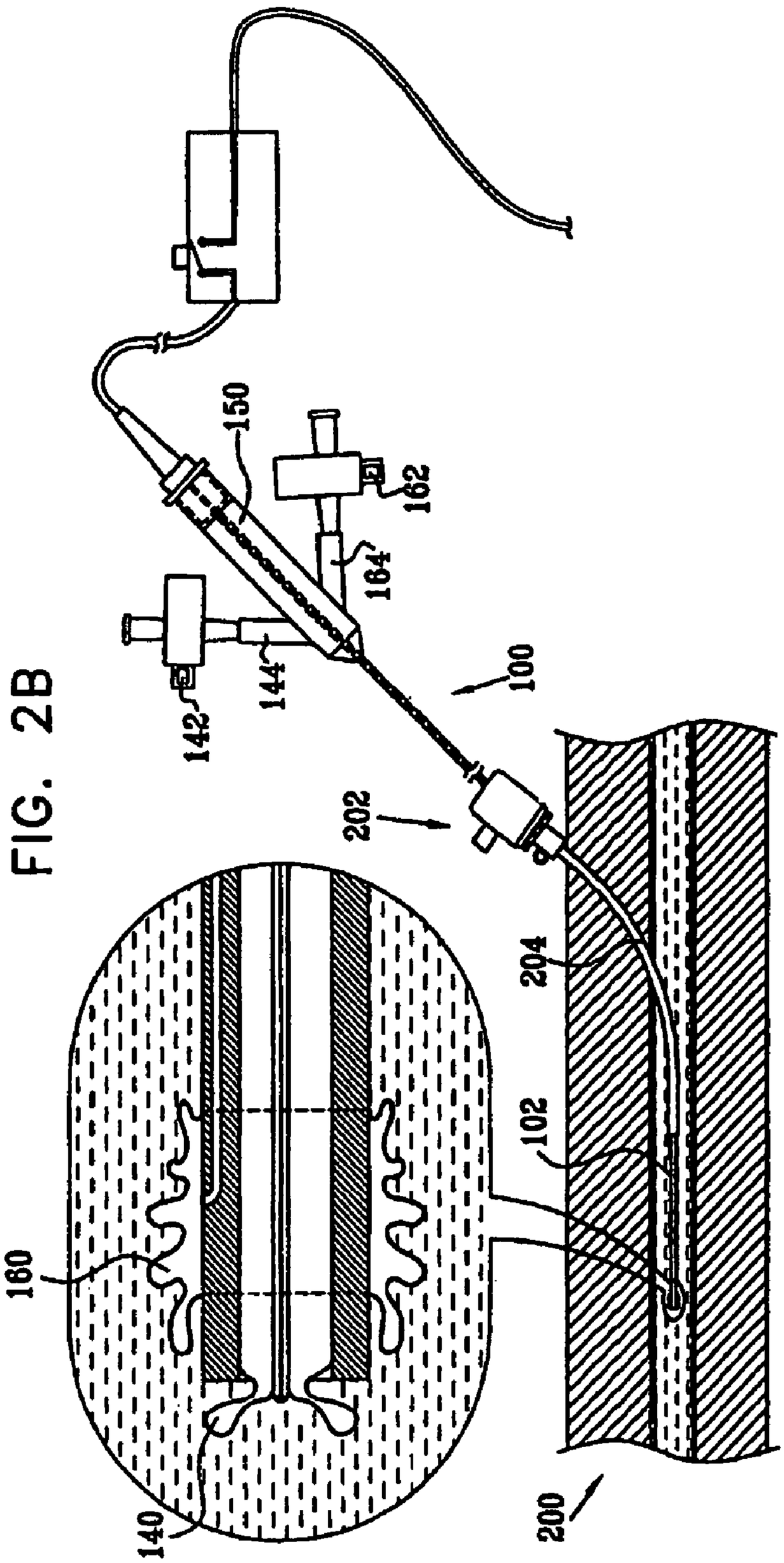


FIG. 2A

FIG. 2B



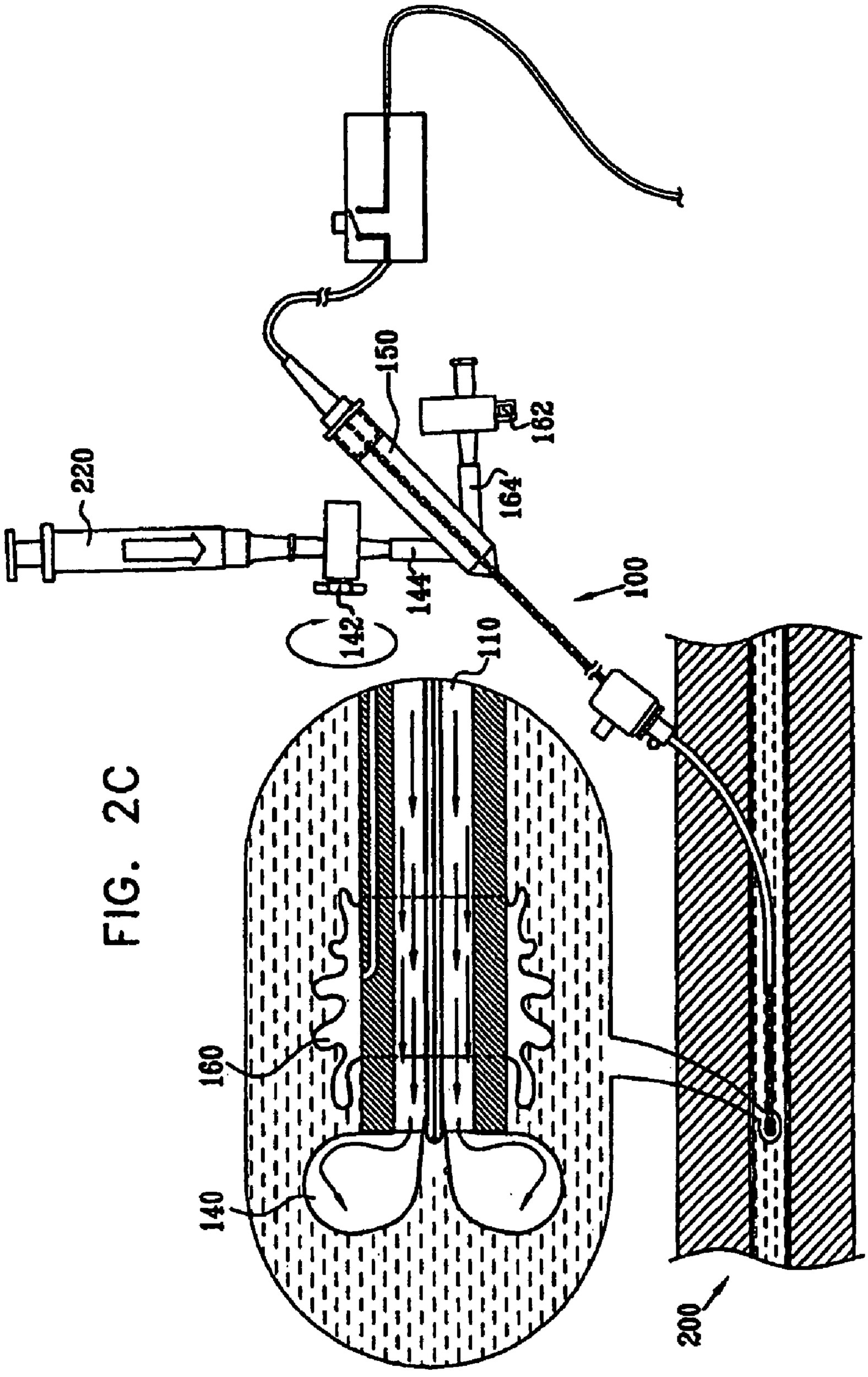
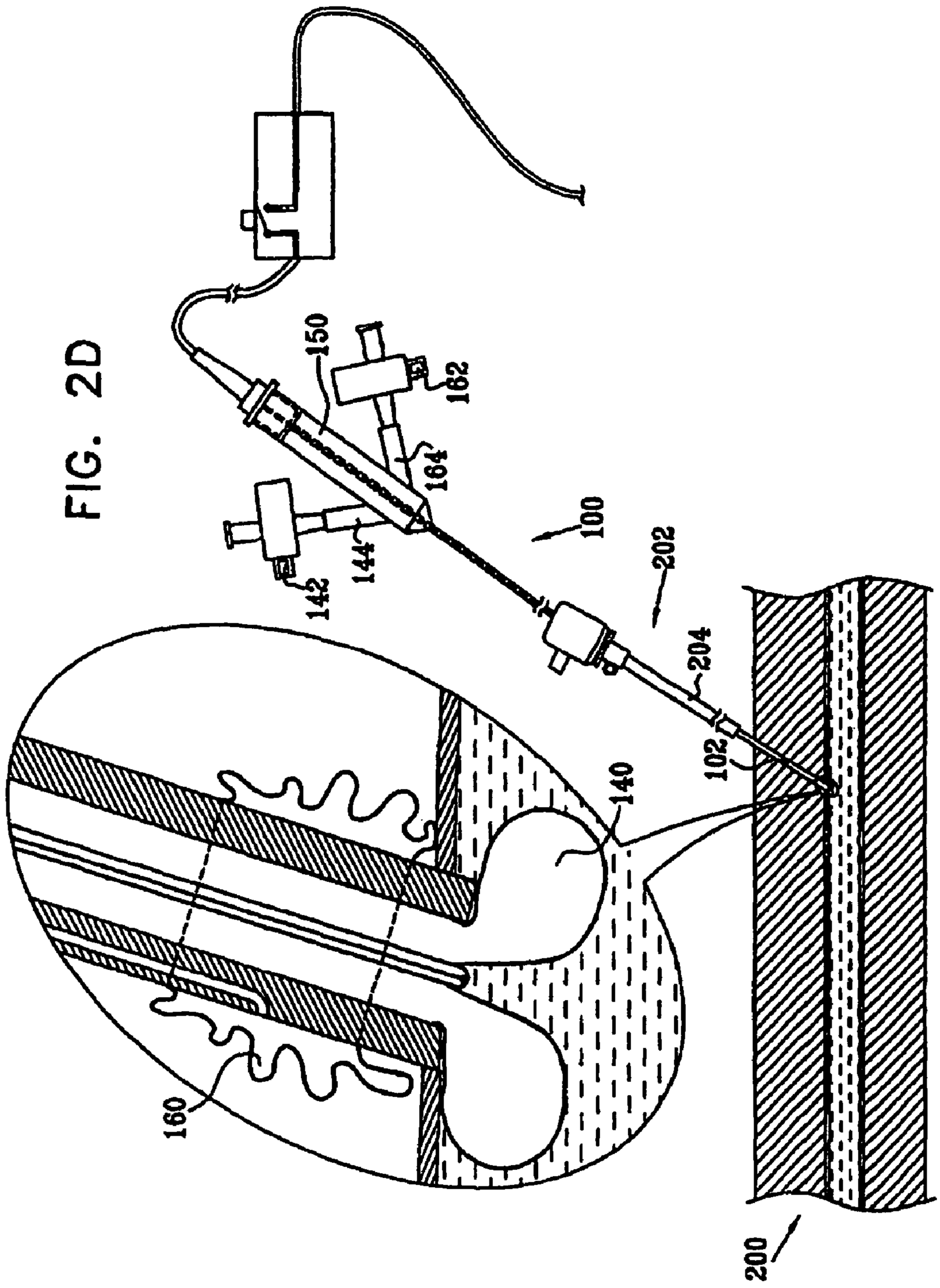
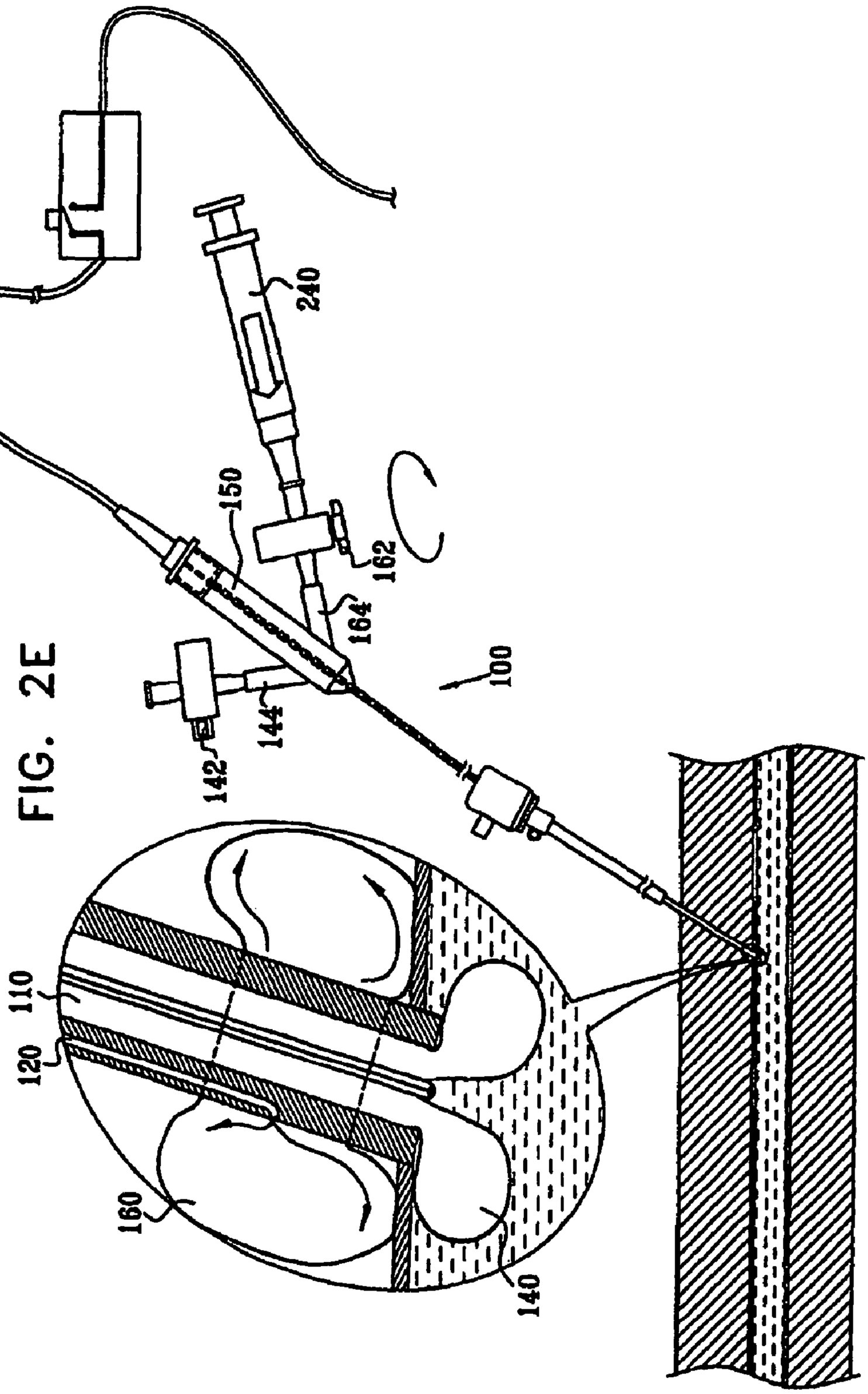


FIG. 2C

FIG. 2D





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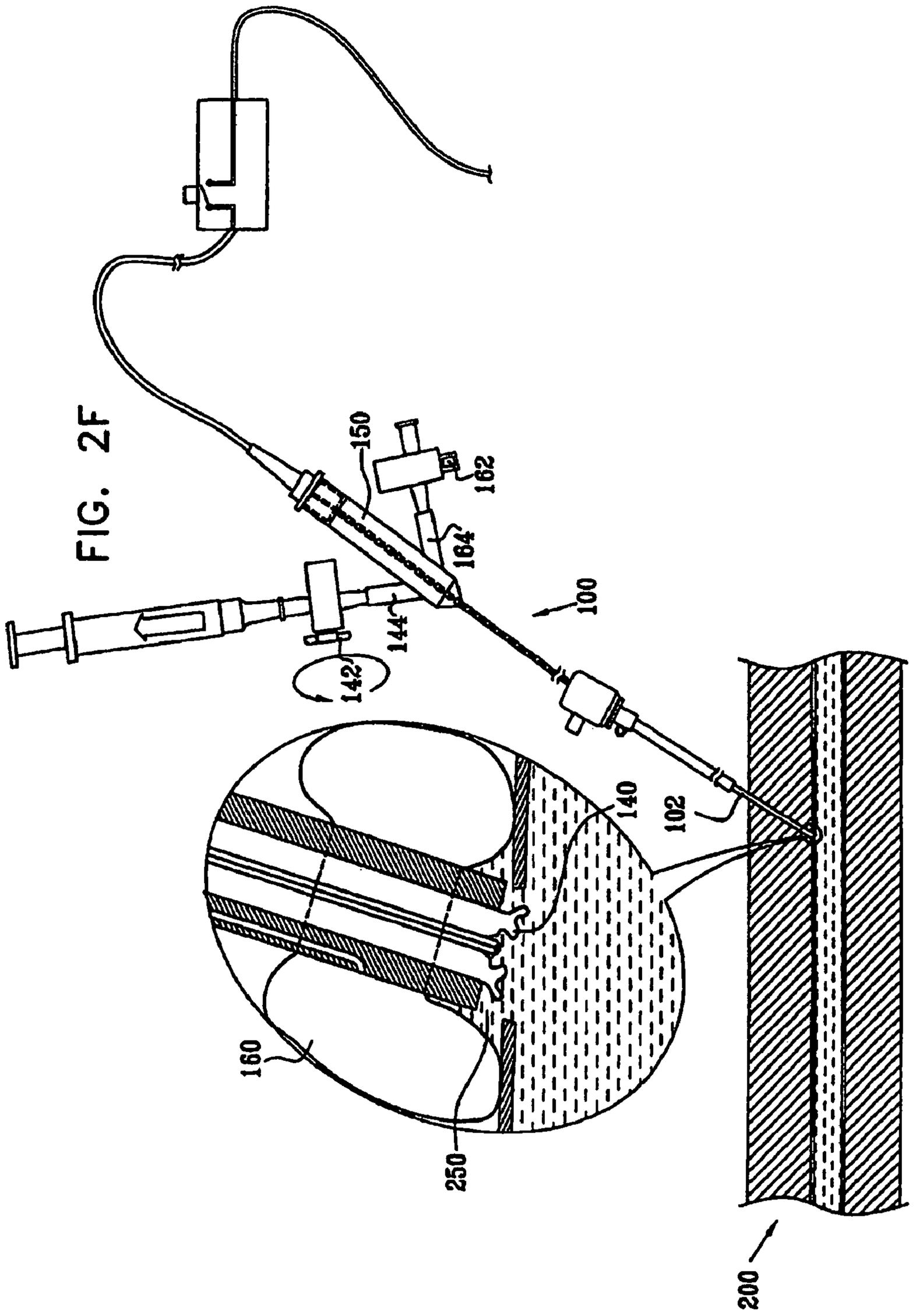
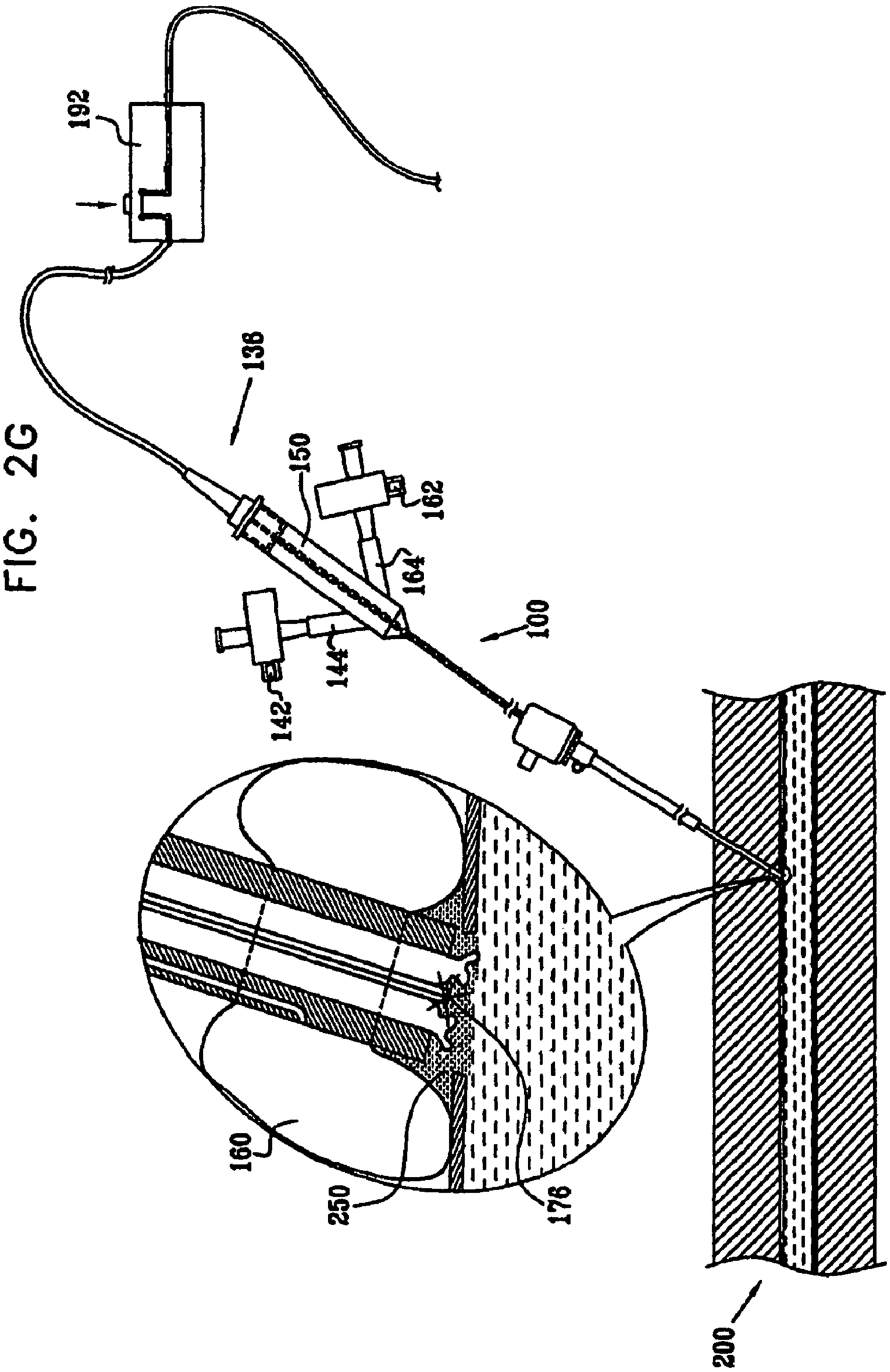


FIG. 2F

FIG. 2G



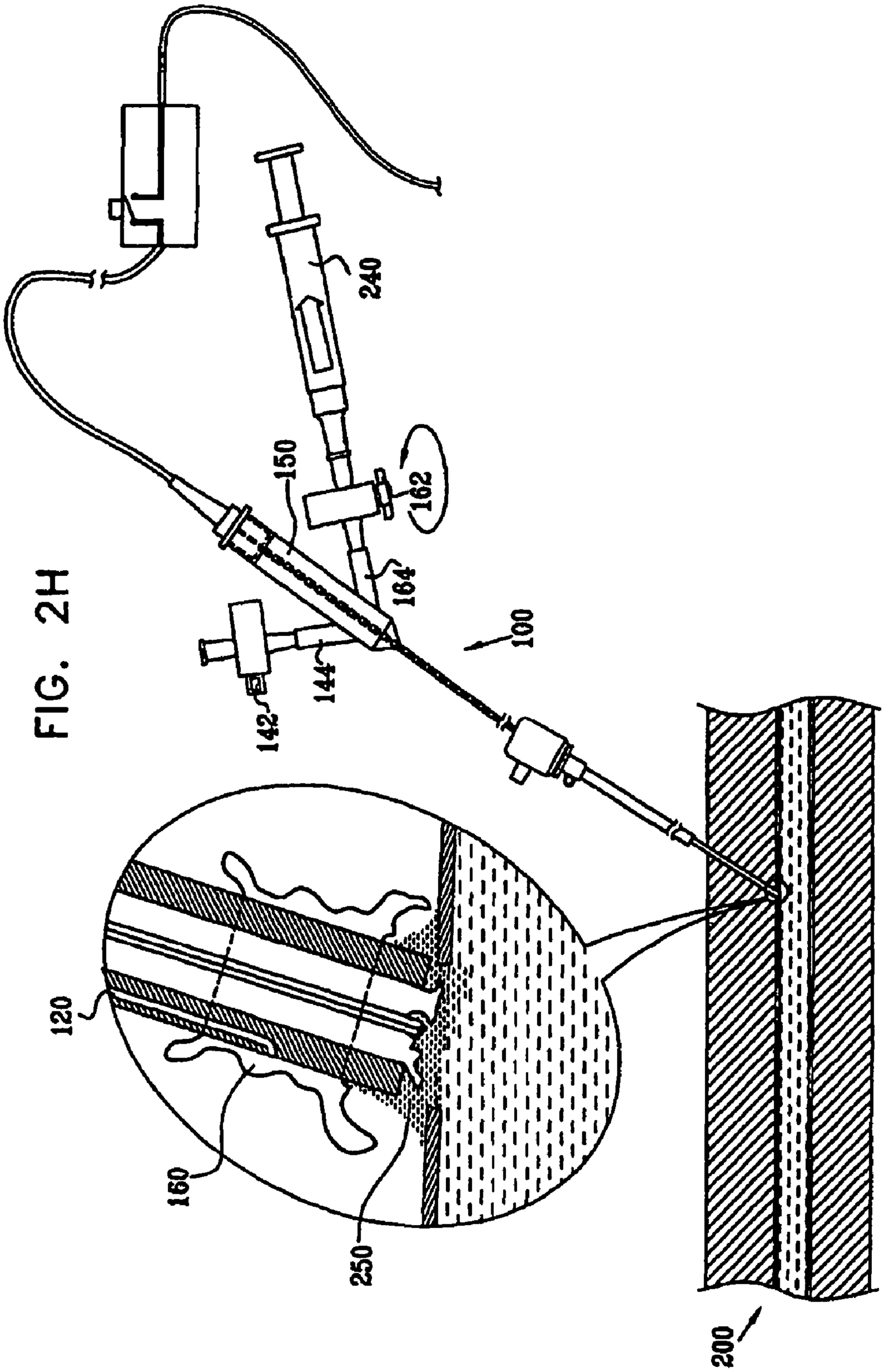


FIG. 2H

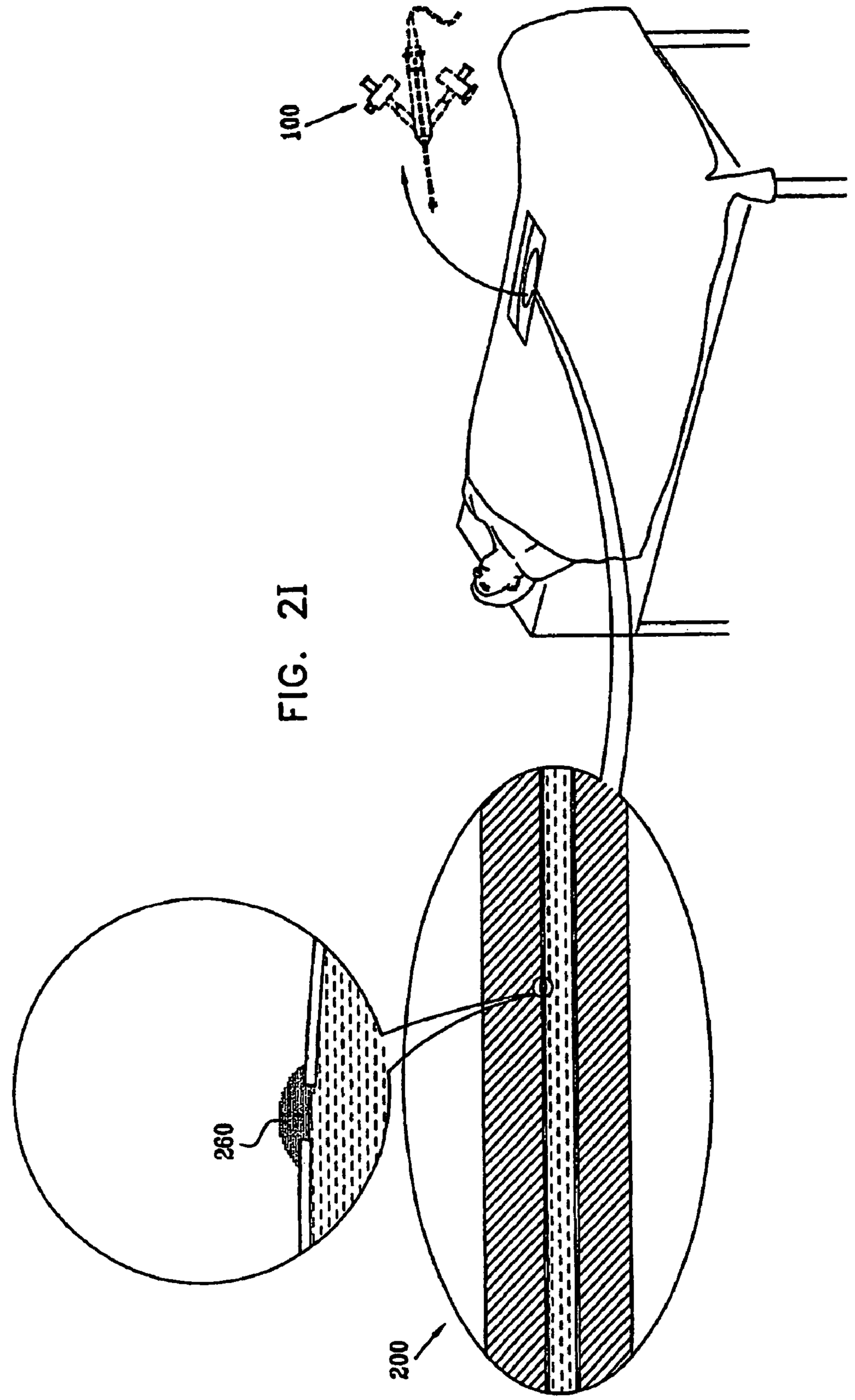


FIG. 2I

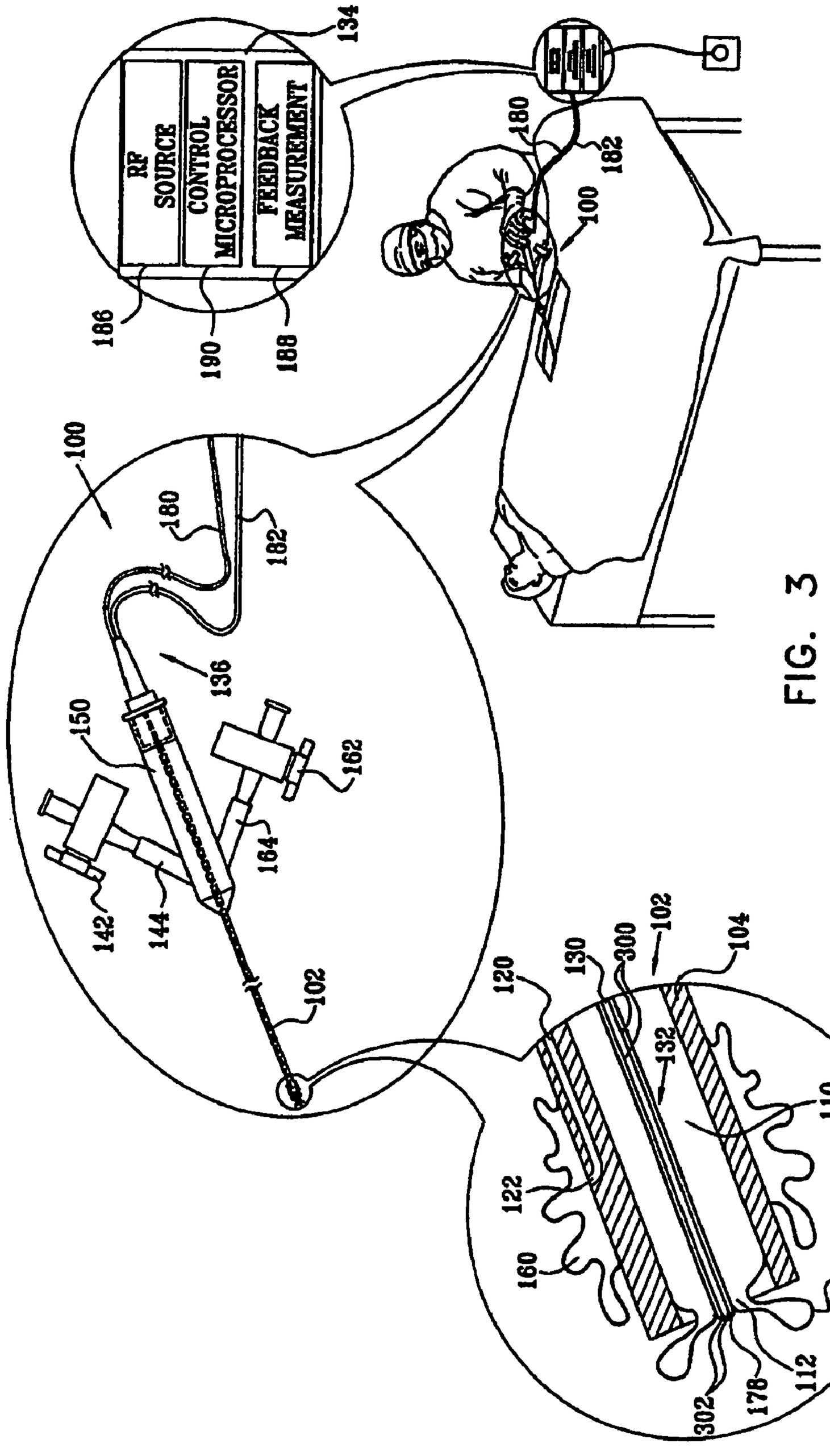

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FIG. 3

METHODS AND APPARATUS FOR HEMOSTASIS FOLLOWING ARTERIAL CATHETERIZATION

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 11/797,294, filed May 2, 2007, now abandoned, which is a continuation U.S. application Ser. No. 10/616,887, filed Jul. 10, 2003, now U.S. Pat. No. 7,223,266, which is a continuation-in-part of U.S. application Ser. No. 10/358,130, filed Feb. 4, 2003, now U.S. Pat. No. 7,115,127, the contents of each are incorporated by reference.

FIELD OF THE INVENTION

The present invention relates to catheterization systems and methodologies generally and more particularly to post-catheterization closure.

BACKGROUND OF THE INVENTION

Various techniques are known for arterial catheterization. Following arterial catheterization, it is necessary to promote hemostasis quickly and without undue hardship for the patient.

Applicant's U.S. Pat. Nos. 5,728,134 and 6,048,358, and Published PCT Patent Applications WO 98/11830 and WO 00/02488 describe methods and apparatus for hemostasis that greatly simplifies hemostasis and thus greatly reduces patient discomfort following arterial catheterization. These patent documents, the disclosure of which are hereby incorporated by reference, and the prior art referenced therein are considered to represent the state of the art.

SUMMARY OF THE INVENTION

The present invention seeks to provide improved systems and methodologies for post-catheterization closure.

There is thus provided in accordance with a preferred embodiment of the present invention a method for producing hemostasis of an artery of a patient having a puncture following arterial catheterization including introducing a hemostasis device including at least one electrode into the vicinity of the puncture, supplying an electric current to the at least one electrode, thereby heating a volume of blood in the vicinity of the puncture, causing coagulation of the blood and causing closure of the puncture and subsequently removing the hemostasis device from the patient.

In accordance with another preferred embodiment of the present invention the at least one electrode includes a pair of electrodes.

In accordance with yet another preferred embodiment of the present invention the introducing includes introducing via a catheter introducer. Additionally, the introducing also includes inflating an anchor balloon attached to an end of the hemostasis device. Alternatively or additionally, the introducing also includes inflating a peripheral balloon. In accordance with still another preferred embodiment of the present invention the removing the hemostasis device includes deflating the peripheral balloon.

In accordance with another preferred embodiment of the present invention the introducing also includes positioning the at least one electrode in close proximity to the volume of blood.

Preferably, the supplying includes supplying electrical power at RF frequencies. Additionally, the electrical power includes electrical power in the range of 0.1-10 watts at up to 25 volts.

In accordance with yet another preferred embodiment of the present invention the supplying also includes adjusting the electric current based on a feedback measurement.

There is also provided in accordance with another preferred embodiment of the present invention a hemostasis device including a main shaft, at least one balloon and at least one electrode, operable to supply an electric current and to thereby heat a volume of blood adjacent to the at least one electrode and to cause coagulation of the blood and closure of the puncture.

In accordance with another preferred embodiment of the present invention the at least one balloon includes at least one anchor balloon, disposed at an end of the main shaft and at least one peripheral balloon, disposed at a location along the main shaft exterior to a wall of the main shaft. Preferably, the volume of blood is delimited by the peripheral balloon and a wall of the artery.

In accordance with yet another preferred embodiment of the present invention the hemostasis device also includes an electrical power source and control module. Additionally, the electrical power source and control module includes a power supply, operative to supply power to the at least one electrode, feedback measurement means and a processor.

Preferably, the power supply includes an RF power supply which supplies electrical power at RF frequencies within a range of 0.1-10 watts at up to 25 volts.

In accordance with still another preferred embodiment of the present invention the feedback measurement means is operative to measure at least one of electrical current, blood resistance and blood temperature.

Additionally, the processor is operative to adjust the power based on an output from the feedback measurement means.

In accordance with yet another preferred embodiment of the present invention the at least one electrode includes a pair of electrodes.

There is further provided in accordance with yet another preferred embodiment of the present invention a method for producing hemostasis of an artery of a patient having a puncture following arterial catheterization, including introducing a hemostasis device including at least one electrode into the vicinity of the puncture, positioning the at least one electrode in proximity with the puncture, supplying an electric current to the at least one electrode, thereby heating a volume of blood in the vicinity of the puncture, causing coagulation of the blood and causing closure of the puncture and subsequently removing the hemostasis device from the patient.

In accordance with another preferred embodiment of the present invention the positioning includes inflating an anchor balloon attached to an end of the hemostasis device, inflating a peripheral balloon and subsequently deflating the anchor balloon. Preferably, the volume of blood is delimited by the peripheral balloon and a wall of the artery.

In accordance with still another preferred embodiment of the present invention the at least one electrode includes a pair of electrodes.

In accordance with yet another preferred embodiment of the present invention the supplying includes supplying electrical power at RF frequencies. Additionally, the electrical power includes electrical power in the range of 0.1-10 watts at up to 25 volts.

In accordance with another preferred embodiment of the present invention the supplying also includes adjusting the electric power based on a feedback measurement.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be understood and appreciated more fully from the following detailed description, taken in conjunction with the drawings in which:

FIG. **1** is a simplified illustration of a hemostasis device constructed and operative in accordance with a preferred embodiment of the present invention;

FIGS. **2**A, **2**B, **2**C, **2**D, **2**E, **2**F, **2**G, **2**H and **2**I are simplified illustrations of the operation of the apparatus of FIG. **1** in a patient treatment context; and

FIG. **3** is a simplified illustration of a hemostasis device constructed and operative in accordance with another preferred embodiment of the present invention.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Reference is now made to FIG. **1**, which is a simplified illustration of a hemostasis device **100** for producing hemostasis following arterial catheterization, in accordance with a preferred embodiment of the present invention. The hemostasis device **100** is suitable for insertion via a conventional catheter introducer (not shown) following completion of catheterization and removal of the catheter from the catheter introducer.

In accordance with a preferred embodiment of the present invention, hemostasis device **100** comprises a main shaft **102**, which has an outer wall **104** and preferably includes at least three bores. A first bore, designated generally by reference numeral **110**, extends along the main shaft **102** to an anchor balloon inflation location **112**. A second bore **120** extends along the shaft **102** to a peripheral balloon inflation location **122**. A third bore, designated generally by reference number **130**, contains an electrocoagulation heating device **132** connected to an electrical power source and control module **134** by a connector **136**.

Disposed at an end of main shaft **102** at anchor balloon inflation location **112** is an anchor balloon **140**. Anchor balloon **140** is selectably inflated, as shown in FIG. **2**C, via a stopcock **142** and associated conduit **144** in fluid communication with main shaft **102** via a head element **150**. Head element **150** is fixed to main shaft **102** at an end thereof opposite the end at which anchor balloon **140** is located. The interior of head element **150** is in fluid communication with first bore **110** in main shaft **102**, which in turn is in fluid communication with the interior of the anchor balloon **140** at anchor balloon inflation location **112**.

Disposed adjacent the end of second bore **120** in fluid communication with peripheral balloon inflation location **122**, exterior of wall **104**, is a peripheral balloon **160**. Peripheral balloon **160** is selectably inflated, as shown in FIG. **2**E, via second bore **120**, via a stopcock **162** and associated conduit **164** that communicate with second bore **120** via head element **150**.

In accordance with a preferred embodiment of the present invention, electrocoagulation heating device **132** comprises an electrical conductor **170** connected to an electrocoagulation electrode **176** at an extreme end **178** of third bore **130**. A pair of electrical cables **180** and **182** extend from electrical power source and control module **134**. In the illustrated embodiment, electrical cable **180** serves as a power supply cable and is connected to electrocoagulation heating device **132** by connector **136**. Electrical cable **182** serves as a return current cable and is preferably connected to an electrode **184** attached to a body of a patient.

Electrical power source and control module **134** preferably comprises a power supply, preferably an RF power supply source **186**, including a feedback measurement circuit **188**. The feedback measurement circuit **188** is preferably operative to measure current, blood resistance or blood temperature and thereby determine progress of hemostasis. The electrical power source and control module **134** also preferably includes a microprocessor **190**, operative to adjust the power supplied to hemostasis device **100** according to the blood temperature or other feedback measurement received from feedback measurement circuit **188**, in order to achieve optimal coagulation of the blood.

In accordance with a preferred embodiment of the present invention an operator actuation switch **192** is connected along electrical cable **180**. In accordance with another preferred embodiment, switch **192** may be obviated and electrical cable **180** connected directly to connector **136**.

Reference is now made to FIGS. **2**A-**2**I, which illustrate various steps in a preferred mode of operation of the apparatus of FIG. **1**.

FIG. **2**A illustrates the hemostasis device **100** about to be inserted into an artery **200** via a conventional catheter introducer assembly **202**, following completion of a catheterization procedure and withdrawal of a catheter (not shown) from the catheter introducer assembly **202**. The catheter introducer assembly **202** conventionally includes a catheter introducer sheath **204**.

FIG. **23** shows the hemostasis device **100** inserted into the catheter introducer assembly **202** such that the outer end of the main shaft **102** extends into the artery **200** well beyond the end of catheter introducer sheath **204**. As shown with particularity in FIG. **2**B, at this stage both anchor balloon **140** and peripheral balloon **160** are deflated.

Reference is now made to FIG. **2**C, which shows initial inflation of the anchor balloon **140**, preferably by use of a syringe **220** communicating with first bore **110** via the interior of head element **150**, stopcock **142** and associated conduit **144**. The inflated anchor balloon **140** preferably has a cusp-type configuration as seen with particularity in FIG. **2**C.

Following inflation of the anchor balloon **140**, the catheter introducer assembly **202** and the hemostasis device **100** are both withdrawn, such that the catheter introducer sheath **204** is removed from artery **200** only when the anchor balloon **140** already engages the interior wall of artery **200** in sealing engagement with the aperture in the artery **200** through which the catheter introducer sheath **204** is drawn and through which the main shaft **102** presently extends. This stage is shown in FIG. **2**D.

As seen in FIG. **2**E, initial inflation of the peripheral balloon **160** is effected, preferably by use of a syringe **240** communicating with second bore **120** via head element **150**, stopcock **162** and associated conduit **164**.

Thereafter, as seen in FIG. **2**F, the anchor balloon **140** is deflated and the peripheral balloon **160** is more fully inflated, which preferably causes the extreme end of the main shaft **102** to be withdrawn from the artery **200** to a location lying just outside the artery wall. As seen in FIG. **2**F, peripheral balloon **160** is preferably designed to allow a limited volume of blood to collect outside of the artery wall after the anchor balloon **140** is deflated. This volume of blood is located in a region, indicated by reference numeral **250**, delimited by the engagement of peripheral balloon **160** with the artery wall.

At this stage, electric power is supplied to the electrode **176** to provide heating of the blood in region **250**, causing coagulation thereof, as seen in FIG. **2**G. In accordance with the illustrated embodiment of FIG. **1** and as shown in FIG. **2**G, the electric power is provided by actuation of switch **192**. In

accordance with another preferred embodiment, switch **192** is obviated, and the electric power is provided by connecting electrical cable **180** (FIG. **1**) directly to connector **136**.

Preferably, the amount of electrical power supplied along electrical cable **180** (FIG. **1**) from electrical power source and control module **134** to the electrocoagulation electrode **176** is between 0.1-10 watts at up to 25 volts at RF frequencies.

Once acceptable hemostasis has occurred in region **250**, the peripheral balloon **160** is deflated, as shown in FIG. **2**H, preferably by operation of syringe **240** communicating with second bore **120** via head element **150**, stopcock **162** and associated conduit **164**.

Thereafter, the hemostasis device **100** is entirely withdrawn from the patient, leaving a region **260** of hemostasis outside of artery **200**, as shown in FIG. **2**I.

Reference is now made to FIG. **3**, which is a simplified illustration of a hemostasis device constructed and operative in accordance with another preferred embodiment of the present invention. The embodiment of FIG. **3** is similar to that of FIG. **1**, except as described hereinbelow. Elements that occur in both embodiments are identified by the same reference numerals.

In the embodiment of FIG. **3**, electrocoagulation heating device **132** comprises a pair of separate electrical conductors **300** extending along third bore **130** connecting electrical power source and control module **134** to a pair of electrocoagulation electrodes **302** at end **178** of third bore **130**. Electrical cables **180** and **182** are both connected to electrocoagulation heating device **132** by connector **136**. The illustrated embodiment shows connector **136** directly connected to electrical cables **180** and **182**.

In the embodiment of FIG. **3**, the electrodes **302** may be arranged in mutual coaxial arrangement or in mutual side-by-side arrangement or any other suitable arrangement.

It will be appreciated by persons skilled in the art that the present invention is not limited by what has been particularly shown and described hereinabove. Rather the scope of the present invention includes both combinations and subcombinations of the various features described hereinabove and shown in the drawings as well as modifications and further developments thereof which would occur to a person of ordinary skill in the art upon reading the foregoing description and which are not in the prior art.

The invention claimed is:

1. A method for producing hemostasis of an artery of a patient having a puncture following arterial catheterization comprising:

introducing a hemostasis device into a vicinity of the puncture, the hemostasis device comprising:

a main shaft;

an expandable member disposed on the main shaft; and

at least one electrode coupled to the main shaft;

expanding the expandable member to form a region delimited by engagement of the expandable member against an outside of an artery wall;

allowing a limited volume of blood to collect outside the artery wall and within the region;

supplying an electric current to said at least one electrode, thereby heating the region causing coagulation of the limited volume of blood in the region and causing closure of said puncture; and

subsequently removing said hemostasis device from the patient.

2. A method according to claim **1** and wherein said at least one electrode comprises a pair of electrodes.

3. A method according to claim **1** and wherein said introducing comprises introducing via a catheter introducer.

4. A method according to claim **1** and wherein said introducing also comprises inflating an anchor balloon attached to an end of said hemostasis device.

5. A method according to claim **4**, further comprising deflating the anchor balloon.

6. A method according to claim **1** and wherein said removing of said hemostasis device comprises deflating said expandable member.

7. A method according to claim **1** and wherein said introducing also comprises positioning said at least one electrode in close proximity to the region.

8. A method according to claim **1** and wherein said supplying comprises supplying electrical power at RF frequencies.

9. A method according to claim **8** and wherein said electrical power comprises electrical power in the range of 0.1-10 watts at up to 25 volts.

10. A method according to claim **1** and wherein said supplying also comprises adjusting said electric current based on feedback measurement.

11. A method for producing hemostasis of an artery of a patient having a puncture following arterial catheterization comprising:

introducing a hemostasis device into a vicinity of the puncture, the hemostasis device comprising:

a main shaft;

an expandable member disposed on the main shaft; and

at least one electrode coupled to the main shaft;

positioning said at least one electrode in proximity with said puncture;

expanding the expandable member to form a region delimited by engagement of the expandable member against an outside of an artery wall;

allowing a limited volume of blood to collect outside the artery wall and within the region;

supplying an electric current to said at least one electrode, thereby heating the region, causing coagulation of the limited volume of blood in the region and causing closure of said puncture; and

subsequently removing said hemostasis device from the patient.

12. A method according to claim **11** and wherein said positioning comprises:

inflating an anchor balloon attached to an end of said hemostasis device;

and subsequently deflating said anchor balloon.

13. A method according to claim **11** and wherein said at least one electrode comprises a pair of electrodes.

14. A method according to claim **11** and wherein said supplying comprises supplying electrical power at RF frequencies.

15. A method according to claim **14** and wherein said electrical power comprises electrical power in the range of 0.1-10 watts at up to 25 volts.

16. A method according to claim **11** and wherein said supplying also comprises adjusting said electric current based on a feedback measurement.

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